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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,544

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Eugene B. Chang

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EXAMINER

MI, QIUWEN

ART UNIT

PAPER NUMBER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,544	<b>Applicant(s)</b> CHANG ET AL.	
	<b>Examiner</b> QIUWEN MI	<b>Art Unit</b> 1655	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7-16,25,27,28,36,38,40-45,47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) 13-16,25,27,40,41,43-45,47 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7-12,28,36,38 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/16/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendment in the reply filed on 2/4/08 is acknowledged.

The previous 112, 2<sup>nd</sup> rejection over claims 2, 12, and 39 was removed due to applicant's amendment to the claims.

The previous 102 (e) rejection over Raz was removed due to applicant's convincing arguments in traversal of the rejection.

### **Claims Pending**

Claims 4, 6, 17-24, 26, 29-35, 37, 39, and 46 are cancelled. Claims 1-3, 5, 7-16, 25, 27, 28, 36, 38, 40-45, 47, and 48 are pending. Claims 13-16, 25, 27, 40-41, 43-45, 47, and 48 are withdrawn as directed toward non-elected inventions. Claims 1-3, 5, 7-12, 28, 36, 38, and 42 are examined on the merits.

### **Claim Objections**

Claims 5 and 7 are objected to because of the following informalities: Claims 5 and 7 recite "claim 4" and "claim 6" respectively, which is incorrect, as claims 4 and 6 have been cancelled. Appropriate correction is required.

### **Claim Rejection 112, 1<sup>st</sup>**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 7-12, 28, 36, 38, and 42 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Applicant argues that Examiner has not met the burden of establishing a prima facie basis for rejecting the claims as lacking adequate written descriptive support (page 2, 1<sup>st</sup> paragraph). Applicant also argues that the supporting disclosure clarified that the inventors had not purified a nucleic acid that was then claimed without providing its primary structure (page 1, last paragraph). In other words, Applicant has claimed an isolated compound without purify the compound, without knowing the structure of the compound, and without even knowing the name of the compound, and that is exactly why Applicant does not have the possession of the claimed invention, namely, an isolated compound, what Applicant really has is an extract or a mixture, not an isolated compound.

Claims 1-3, 5, 7-12, 28, 36, 38, and 42 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an extract from a medium, does not reasonably provide enablement for an isolated compound.

Applicant argues that “isolated does not mean purified to homogeneity, an isolated compound can be a compound separated from a single composition with which it is normally found. Thus, a medium extract containing a compound from a Lactobacillus bacterium satisfied the ordinary meaning of an isolated compound” (page 3, 2<sup>nd</sup> paragraph).

This is not found persuasive. One of the ordinary skills in the art would interpret “isolated compound” as separating a compound in pure form from a combined mixture (see dictionary .com) through purification and structure elucidation.

Applicant further argues that the claims do not recite an isolated form of each compound of an organism, and the vast majority of compounds isolable from any organism would not exhibit the set of identifying characteristics as claimed (page 3, last paragraph). Applicant further states that one of the skills in the art would know the activity and dosage determination.

This is not found persuasive. If isolating a pure compound with the claimed characteristics is such an easy thing, why hasn't Applicant have accomplished that? Pinpoint the claimed activity to a particular compound from an extract takes more than routine optimization, and that's why so many natural products are not in the form of pure compounds. Thus, what Applicant enables for is an extract from a medium, not an isolated compound.

### **Claim Rejections –35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 12, 28, and 42 remain rejected under 35 USC § 102 (e) as being anticipated by Versalovic et al. (US 2004/0208863) as evidenced by JP 2000236873\*, Hamburger (US 1,459,359)\*, and Bailey et al (4,771,001)\*.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 8/2/2007, slightly altered to take into consideration Applicant's amendment filed on 2/4/08. The prior arts cited also teach the newly amended claim limitation.

Versalovic et al explicitly teach that many different lactic acid are known to produce various factors that gave anti-inflammatory effects [0013]. Versalovic et al also teach VSL#3 medium, and the medium is inherently conditioned by *Streptococcus thermophilus*, *Lactobacillus* and *Bifidobacterium*.

As evidenced by Bailey et al, lactic acid is heat-stable (col 1, lines 40-45).

Applicant argues that "Use of a lactic acid bacterium to deliver lactic acid means that the lactic acid being delivered is not "isolated," as required by the pending claims. In addition, the Examiner has not shown that lactic acid is an inhibitor of NF-Kappa B activation" (page 5, 1<sup>st</sup> paragraph).

This is not found persuasive. Versalovic et al specifically teach that "the invention here comprises a compound secreted from lactic acid bacterial that comprises anti-inflammation activity" [50]. Versalovic et al further teach that "the active compounds may be formulated into a composition in a neutral or salt form" [0101]. Thus the compound is "isolated", not in a mixture or extract. Further more, "wherein the compound is an inhibitor of NF-kappaB activation" is the intended use of the compound which does not carry patentable weight. In addition, as evidenced by Karin (The NF-Kappa B activation pathway: its regulation and role

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in inflammation and cell survival, Cancer Journal from Scientific American, 4 (suppl. 1): S92-9, 1998), it is well known in the art that anti-inflammatory compound is an inhibitor of NF-Kappa B (see the whole document).

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

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### Conclusion

-----No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi

/Patricia Leith/

Primary Examiner, Art Unit 1655